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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,687

04/26/2005

Wing Sum Cheung

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

05/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,687	Applicant(s) CHEUNG, WING SUM	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008 and 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 3/2/09 to claims 1, 11, 14, and 15 have been entered. Claim 12 has been cancelled (not claim 13, as applicant's reply at page 2 indicates). Claim 16 has been added. Claims 1-11 and 14-16 remain pending in the current application, all of which are being considered on their merits. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 14-16 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Shibayama et al. (1991, U.S. Patent 5,057,324).

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (column 1, lines 45-65) and removing the skin (Example 1 at column 2, line 57, et seq.). Shibayama teaches treating the skin first with sodium hydroxide (an alkali) and then with hydrochloric acid, then subjecting it to ultrafiltration to remove substances of molecular

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weight greater than 20kDa (column 3, lines 1-12). Shibayama teaches adding distilled water to the resulting ultrafiltrate (column 3, lines 13-22) and claim a composition comprising the product and a pharmaceutically acceptable carrier (claim 8).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since

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in spite of the fact that the claim may recite only process limitations, **it is the patentability of the product claimed and not of the recited process steps which must be established.** We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, there is no evidence on the record that the strain of vaccinia virus or the strain of rabbit has any effect on patentability. The data in the table at page 14 is noted, but there is no evidence that the variations in base and amino acid composition from the different combinations has any effect on the patentability of the product, e.g. an effect on SART that affects patentability.

Applicant alleges that since Shibayama does not teach the claimed SART activity, it cannot anticipate the claims (Reply, pages 7-8). These arguments have been fully considered, but they are not persuasive. The instant claims are product-by-process claims, so the patentability of the product must be established by applicant based on evidence. See bolded, underlined portion in above paragraph and M.P.E.P. § 2113.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 14-16 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shibayama et al. (1991, U.S. Patent 5,057,324).

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (column 1, lines 45-65) and removing the skin (Example 1 at column 2, line 57, et seq.). Shibayama teaches treating the skin first with sodium hydroxide (an alkali) and then with hydrochloric acid, then subjecting it to ultrafiltration to remove substances of molecular weight greater than 20kDa (column 3, lines 1-12).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different

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than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

The reference does not explicitly teach feeding the rabbit. However as a matter of standard protocol, animals used in laboratory experiments are required to be treated humanely which includes feeding of the animals. Thus, while the reference does not expressly state the rabbits were fed, it would have been a matter of standard procedure to do so, and thus obvious to one of ordinary skill in the art.

The reference does not teach each of the claimed strains of vaccinia, types of rabbit, wherein the inflammation reaches the claimed point, or SART activity of the skin. However, at the time of the claimed invention, each of the claimed strains and rabbits were well known and used in the art for animal and laboratory experiments. Thus, it would have been within the purview of one in the art to use any of the instant strains or rabbits as a matter of routine practice. Regarding the SART activity, the skin of the art is the same as that claimed, thus it must intrinsically exhibit the claimed activity.

The reference does not teach the amount of virus injected into the rabbit. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such injections as a matter of routine experimentation. Thus, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of virus injected into the rabbit with a reasonable expectation for successfully obtaining an effective extract against the formation of kallikrein.

The reference does not teach water as the pharmaceutically acceptable carrier. However, at the time of the claimed invention, water was a well known and recognized carrier. Thus it would have been obvious to one of ordinary skill in the art to combine the extract with water in following the teachings of Shibayama.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges, "It is well settled that the failure of a reference to disclose or suggest a claimed property, let alone a recited range of such a property, supports nonobviousness of the claim" (Reply, pages 8-9). Applicant implies that the process steps impart patentability to the product (Reply, page 9). These arguments have been fully considered, but they are not persuasive.

The basis for applicant's statement about what is "well settled" is not clear. Applicant has cited no relevant portion of the M.P.E.P. or any case law, and a search of the M.P.E.P. found no guidance to support applicant's claims regarding the disclosure of the art regarding properties of compositions. M.P.E.P. § 2113 is quite clear that in product-by-process claims, the patentability of the composition and not that of the steps must be established by applicant once a substantially identical product is found by the examiner. Applicant has not met the burden required by M.P.E.P. § 2113.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651